§ 886.5925 Soft (hydrophilic) contact lens.

(a) *Identification.* A soft (hydrophilic) contact lens is a device intended to be worn directly against the cornea and adjacent limbal and scleral areas of the eye to correct vision conditions or act as a therapeutic bandage. The device is made of various polymer materials the main polymer molecules of which absorb or attract a certain volume (percentage) of water.

(b) *Classification.* (1) Class II if the device is intended for daily wear only.

(2) Class III if the device is intended for extended wear.

(c) *Date PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the act is required before a device described in paragraph (b)(2) of this section may be commercially distributed. See § 886.3.

[52 FR 33355, Sept. 2, 1987, as amended at 59 FR 10284, Mar. 4, 1994]

§ 886.5928 Soft (hydrophilic) contact lens care products.

(a) *Identification.* A soft (hydrophilic) contact lens care product is a device intended for use in the cleaning, rinsing, disinfecting, lubricating/rewetting, or storing of a soft (hydrophilic) contact lens. This includes all solutions and tablets used together with soft (hydrophilic) contact lenses and heat disinfecting units intended to disinfect a soft (hydrophilic) contact lens by means of heat.

(b) *Classification.* Class II (Special Controls) Guidance Document: ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.''

[62 FR 30988, June 6, 1997]

§ 886.5933 [Reserved]

PART 888—ORTHOPEDIC DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Diagnostic Devices

Subpart C [Reserved]

Subpart D—Prosthetic Devices